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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,120

Applicant(s)

SCHILLING ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Amendments filed on December 13, 2003 is acknowledged. Claims **33-41** are pending in this application. Claims 1-32 stand cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites a process wherein cartilage is combined with an antimicrobial agent and salt, which is followed by heating the cartilage. The claim then recites, "recovering a product...in its original form." It is unclear how a product that has undergone heat treatment, i.e. dehydration, can be recovered in its original form. A dehydrated product is not in its original form since the original form has other constituents such as water, that have been removed.

Step (a) of claim 33 recites, "at least 15% by weight of the cartilage of an ionizing salt", which is unclear. It is unclear what the 15% is referring to. Is it referring to the cartilage or the salt? If the latter is intended, the examiner suggests re-writing the limitation to read "at least 15% by weight of an ionizing salt." Further, step (a) recites, "combining *such* substances with...", which is unclear as to what substances the applicant is referring to. The examiner suggests re-writing the claim to read: "combining [collagen II containing cartilage] with an antimicrobial...."

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Step (b) of claim 33 recites, "a temperature below which denaturization occurs". It is unclear what this is referring to. Is the denaturization referring to the Type II collagen or the cartilage? Cartilage contains other active substances such as Type I collagen, therefore it is unclear what exactly the denaturization is referring to. If the applicant is referring to denaturization of the Type II collagen, the examiner suggests reciting "at a temperature below which denaturization [of Type II collagen occurs.]" Furthermore, step (b) recites "until the water content is reduced to below 15% by weight of the dried cartilage". "The dried cartilage" lacks antecedent basis and implies that the cartilage utilized is dehydrated to begin with. The examiner suggests re-writing the phrase to read "until the water content is reduced to below 15% by weight of the cartilage."

Step (c) of claim 33 recites "and having a salt and having a salt content of at least 45% by weight of the cartilage", which it is unclear as to what exactly the limitation is since cartilage that has been combined with salt already has a salt content.

Lastly, in regards to claim 33, it should be noted that all claims must end with a period. Appropriate correction is required.

Claim 39 recites a process wherein cartilage is pulverized, then combined with an antimicrobial agent and salt, which is followed by heating the cartilage. The claim then recites, "recovering a containing the protein of the chicken cartilage in its natural form. Firstly, the phrase is unclear due to grammatical and typographical errors. Secondly, it is unclear how a product that has undergone pulverization and heat treatment, i.e. dehydration, can be recovered in its original form. A pulverized and

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dehydrated product is not in its original form since the original form is in a whole form and contains other constituents such as water.

Step (a) of claim 33 recites, "comminuting such" which is unclear as to what 'such' is referring to. The examiner suggests re-writing the claim to read: "comminuting the [chicken cartilage]".

Step (c) of claim 33 recites "the dried product", which lacks antecedent basis and implies that the cartilage utilized is dehydrated to begin with. The examiner suggests re-writing the phrase to read, "until the water content of the cartilage is reduced to below 10%."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (5,645,851) in view of Ueno et al (4789497) or in view of JP 59025637, optionally in further view of Puppolo (5,562,535).

Moore teaches the obtaining Type II collagen from chicken cartilage (abstract). The chicken is soaked in a solution containing 5.15% sodium hypochlorite and water to remove surface contamination. The cartilage is removed from the chicken flesh and soaked in hydrogen peroxide to sterilize the cartilage without denaturing the protein. The product is diced. (Note example 1). The product of example 1 can be dried at an

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average temperature of 110 Fahrenheit to remove over half the water content (example 12). These samples have the advantage of improved shelf life, reduced volume, and better handling.

Moore does not specify the water content. Additionally, Moore does not teach adding salt during the sterilization/washing step.

Ueno et al teach the process of dehydration of fish meat. Ueno discloses the "well-known method" to improve dehydration, is to add sodium chloride, magnesium chloride, or calcium chloride at the time of washing. This promotes the bonding of proteins with Na, Mg, or Ca ions resulting in reduction in the charge of proteins and eases dehydration by the removal of water. Ueno et al teaches the object of washing is to remove factors that cause denaturization of proteins (col. 1, line 16 and lines 44-50). Ueno teaches the amount of salt in the Tables.

JP teaches treating scallops by dehydrating using salt. JP teaches using 7-15% salt to dehydrate the ligaments of scallops.

Puppolo teaches a method of producing dehydrated shark cartilage without denaturing the proteins. The reference teaches that prior art methods of dehydrating such as convection ovens, vacuum ovens, and freeze drying techniques use temperatures that are high enough to cause the loss of proteins (column 1, lines 5-16). After the undesirable components are removed from the cartilage, the removal of all water and solvent is accomplished by drying the product in a sonic chamber at 85 degrees Fahrenheit or lower (col. 2, lines 34-45). This temperature does not denature the proteins and removes all the solvent and water. See column 2, lines 34-35.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the instant salt in Moore's sterilization/washing step before heat dehydration. One would be motivated to add the instant salts to facilitate dehydration and prevent denaturization of the protein during dehydration. Further one would be motivated to do so with the expectation of similar results since both references methods are directed towards preserving the proteins in the end product. Therefore, a skilled artisan would be motivated to add salt to facilitate and hasten the dehydration process.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to JP and utilize the instant amount of salt in Moore's dehydration method. One would be motivated to do so since JP teaches the method of dehydrating ligaments (ligaments inherently contain type II collagen) with salt. Therefore, one would be motivated to add the salt to further facilitate and hasten the dehydration step.

The teachings of Puppolo are relied upon to demonstrate the inherency of the water content amount in Moore's dehydrated cartilage. US patent 5,562,535 to Puppolo discloses the removal of **all** solvent and water in cartilage is accomplished at 85 degrees Fahrenheit. Therefore, Puppolo demonstrates that Moore's product, which is heated at 110 degrees Fahrenheit, would inherently have the instant moisture content.

Furthermore, even if one were to argue that the instant water content is not inherent in Moore, it is deemed an obvious skill in the art to prolong the heating step till

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the desired water content is yielded. One would be motivated to do so since Moore teaches that reducing the water content prolongs the shelf life of the product.

It is the examiner's position that since the prior teaches the utilization of instant 15% salt, it is implicit that the dehydrated product will yield the recites "at least 45%" salt content.

Response to Arguments

Applicant argues that Moore does not teach an ionizing salt to the cartilage itself. It is argued that the salt is not added to the antimicrobial solution and Ueno teaches adding the salt in the washing step. Applicant argues that Moore and Ueno involve different proteins and different methods. Applicant argues that Puppolo teaches a different method of drying and would not suggest any temperatures involving salt.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that new claim 39 recites soaking the cartilage in an aqueous solution of salt and an antimicrobial. Thus, it is not understood how the applicant argues that the salt is not added to the antimicrobial solution since this directly contradicts the instant claim. Furthermore, the argument that the salt is not added to the cartilage is not understood since clearly the washing/sterilizing step involves applying the salt and antimicrobial solutions to the cartilage.

In regards to Ueno, the examiner again points out that the reference is relied upon for the specific teaching of salt in the washing/sterilizing step of Moore and not Ueno's dehydration process. Ueno is further relied upon to demonstrate the state of the art, i.e. conventional use of salt in dehydration processes. This is clear from Ueno's

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statement: "The well-known method to improve dehydration is to add sodium chloride."

The examiner is not utilizing Ueno's method of dehydration or type of protein, which is addressed by Moore's disclosure. Further, it is known that regardless of the type of material being dehydrated, salt is known to dehydrate materials such as animal by products.

JP 59025637 further demonstrated the state of the art wherein it is common to utilize the instant amount of salt for dehydration purposes. It is prima facie obvious to combine two dehydration processes, i.e. heat and salt dehydration, to yield an additive dehydration process.

In regards to Puppolo, the examiner points out that the method of drying the instant claims are not differentiated in the claims from Puppolo's methods. Further, Puppolo is an optional reference, relied upon to demonstrate inherency.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (5,645,851) in view of Ueno et al (4789497) or in view of JP 59025637 in further view of JP 59-088065.

As set forth above, Moore teaches dehydrating cartilage by soaking in an aqueous antimicrobial solution, followed by heating the cartilage to reduce moisture content. Ueno and JP teach the utilization of salt to further dehydrates animal products.

The references do not teach the use of lecithin or cellulose.

JP teaches dehydration of edible bone and marrow. The method includes soaking, disinfecting, and washing the edible parts in sodium hypochlorite for one hour. The parts are ground and mixed with soy lecithin at a temperature that does not

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degrade the protein. See page 2 of translated document. The powder is then hot air dried. The lecithin is utilized to enable easy washing of the product and provide for a uniform solution. See page 2-3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Moore, Ueno or JP 59025637, and JP 59-088065 and utilize lecithin in the process. One would be motivated to do so since JP teaches lecithin enables easy washing of the animal product and provides for a uniform solution prior to dehydration. One would expect similar results since all the references are in the same field of endeavor, i.e. the process of dehydrating animal products.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

Sharmila S. Gollamudi
2/24/04

Michael G. Hartley
MICHAEL G. HARTLEY
PRIMARY EXAMINER